REMARKS

Claims 29-52, 54-55, 57 and 59-73 are pending in the application with entry of this amendment. Claims 29 and 67 are currently amended. The amendments do not introduce new matter. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicants acknowledge that the following rejections have been withdrawn:

A. Rejection of claims under 35 U.S.C. §103(a) as being allegedly being unpatentable over U.S. Patent No. 5,669,905 to Scheldrup *et al.* ("Scheldrup") in view of U.S. Patent No. 6,238,340 to Alt ("Alt").

B. Rejection of claims under 35 U.S.C. §103(a) as being allegedly being unpatentable over Scheldrup in view of Alt and further in view of U.S. Patent No. 5,250,071 to Palermo ("Palermo").

C. Rejection of claims under 35 U.S.C. §103(a) as being allegedly being unpatentable over Scheldrup in view of Alt and Palermo and further in view of U.S. Patent No. 5,569,245 to Guglielmi ("Guglielmi").

D. Rejection of claims under 35 U.S.C. §103(a) as being allegedly being unpatentable over Scheldrup in view of Alt and further in view of U.S. Patent No. 5,814,062 to Sepetka ("Sepetka").

E. Rejection of claims under 35 U.S.C. §103(a) as being allegedly being unpatentable over Scheldrup in view of Alt and further in view of U.S. Patent No. 6,296,636 to Cheng ("Cheng").

II. Rejection Under §101

Applicants respectfully submit that the rejection of claims 29-52, 54, 55 and 59-73 is moot in view of claims 29 and 67 as amended.

Initially, Applicants note that all of the claims are directed to a "system." The system claims recite structural aspects of various system components. Claim 29, for example, recites *inter alia* "a catheter having a proximal end and a distal end, the catheter being insertable within a vascular cavity in the body," "a temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant," and an electrical measurement device "configured to monitor an electrical condition related to a position of the temporary connection," and being further

"configured to generate an output signal…" Claims 29 and 67 also recite, for context, that various system components are configured to perform certain functions when the catheter is inserted into the vascular cavity. Thus, a vascular cavity *per se* is not positively claimed, and no portion of the human body is positively recited in the claims.

The Office Action generally refers to "many more instances" in which a human body is positively recited in the claims, but does not refer to any specific examples. Upon reviewing the claims, Applicants are not able to identify such "instances."

Accordingly, Applicants respectfully request that the rejection under §101 be withdrawn. If the rejection stands, Applicants request the Examiner to identify each claim that allegedly positively recites the human body and the "many more instances" of such claims so that Applicants may address the rejection since the basis of the rejection is not clear.

III. Claims 29-31, 37, 38, 43-45, 47-52, 54, 59-61, 64, 65 and 72 Are Patentable Over Ogawa

Independent claims 29 and 67 and respective dependent claims 30, 31, 37, 38, 43-45, 47-52, 54, 59-61, 64, 65 and 72 stand rejected under 35 U.S.C. §103(a) as being allegedly being unpatentable or obvious over U.S. Patent No. 5,846,210 to Ogawa ("Ogawa"). Applicants acknowledge that independent claim 67, dependent claims 32-36, 39-42, 46, 53, 62, 63 and 66 (which depend from independent claim 29), and dependent claims 68-71 and 73 (which depend from independent claim 67) are not rejected as allegedly being unpatentable over Ogawa. Applicants respectfully traverse the rejection and respectfully submit that Ogawa does not support the Office Action allegations.

Initially, it is conceded that Ogawa fails to disclose, teach or suggest the structural combination of a catheter, a delivery member, an insulative member, and a temporary connection, the "temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant" as recited in claim 29. Office Action (p. 4). Instead, it is generally alleged that it would have been obvious to provide an insulative material between a temporary connection and an implant since the Applicant has not specifically disclosed why this structural configuration solves any stated problem. Office Action (p. 4). Thus, it appears that the Office Action rejection is not based on what is actually disclosed by Ogawa, but rather, what is allegedly not disclosed in the subject application.

Nevertheless, Applicants note that the subject application does indeed explain in detail how an insulative member is configured relative to other system components and how it is utilized, advantageous and addresses problems associated with positioning in implant in a patient's body. The insulative member is part of an insulative chamber that is used to determine whether a temporary connection has reached a predetermined location or position. For example, with reference to Fig. 1, col. 8, line 27 to col. 12, line 26 of subject application explain that the catheter 110 is made of a generally insulative or non-conductive material and defines an inner lumen or cavity 112. The catheter 110 and the insulative member 150 form an "insulative chamber" that prevents or minimizes the amount of current that flows through the delivery member 120 when the member 120 is confined to the catheter lumen 112. An initial electrical condition or parameter 162 in the circuit completed through the body 190 is detected by the measurement device or sensor 160. The magnitude of the current 162 is related to the position of the temporary connection 130 and the implant 140 attached thereto as they are pushed through the lumen 112 of the catheter 110. For example, the current 162 may indicate when the temporary connection 130 reaches or exits the distal tip 116 of the catheter 110.

The power supply 170 provides a voltage V1 that results in a small initial or trickle current I1 162 flowing through the circuit completed through the patient body 190. The initial trickle current I1 162 results from the high resistance of the insulative catheter 110 and insulative member 150, which limit current flow when the conductive detachment zone 130 is located within the catheter 110. As the delivery member 120, temporary connection 130 and implant 140 are pushed through the catheter lumen 112, the temporary connection 130 reaches or passes a predetermined location 180, such as the distal tip 116 of the catheter 110. As a result, the conductive temporary connection 130 exits the "insulative chamber" in the catheter 110 and contacts blood in the vascular space 192 in the body 190, resulting in a larger, second current I2 that flows through the circuit formed by the delivery wire 120, the temporary connection 130, the body 190, and the measurement device 160.

Accordingly, the Office Action allegation that Applicants have not disclosed how the insulative member is used for a particular purpose or solves a problem is not clear since such aspects of the insulative member are explained in detail in the subject application. Applicants respectfully submit that these allegations are misplaced and moot and cannot support the rejection.

Turning to the Office Action allegations regarding what is actually disclosed by Ogawa, as opposed to what is allegedly "not disclosed" by the subject application, it is alleged that the "implant" as recited in these claims is the implanted device 16 described by Ogawa, the "delivery member" is the guide wire 10, the "temporary connection" is the joint member 15. Office Action (p. 3).

It is conceded that Ogawa fails to disclose, teach or suggest the structural combination of a catheter, a delivery member, an insulative member, and a temporary connection, the "temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant" as recited in claim 29, and is generally alleged that such a structural configuration is obvious. Office Action (p. 4). Applicants respectfully disagree, particularly in view of the structural configuration described by Ogawa, and the specific function of the insulated coating 25 (the alleged "insulative member"), which contradict the Office Action allegations.

With reference to Fig. 1 of Ogawa, the cited reference explains that the guide wire 10 includes a proximal part 11, a flexible part 12 and an X-ray impervious part 13. Ogawa (col. 6, lines 8-11). "The joint member is connected to an end of the X-ray impervious part 13." Ogawa (col. 6, lines 8-11). More particularly, a proximal part 15a of the joint member 15 is inserted into a coiled distal part 14 of the guide wire 10 and fixedly connected thereto with an adhesive. Ogawa (col. 6, lines 50-53; Fig. 2). A distal part 15b of the joint member 15 is inserted into a coil portion 16A of the implanted device 16 and fixedly connected thereto with an adhesive. Ogawa (col. 6, lines 62-67; Fig. 2).

With reference to Fig. 6, Ogawa further explains:

> FIG. 6 illustrates another embodiment of the present invention. In this embodiment, an electrically insulated **coating** 25 is provided **on the peripheral surfaces of the flexible part 12 and distal X-ray impervious part 13** in the guide wire 10. This electrically insulated **coating** 25 can be formed by one of various polymers, for example, polyurethane, polyethylene, polypropylene, silicone resins and polyamide resins such as nylon. A hydrophilic polymer coat may be further provided on the coating of this resin. Ogawa (col. 9, lines 35-43) (emphasis added).

> According to the medical wire of such a construction, the implanted device 16 can be detached and deposited by applying a monopolar high-frequency current through the guide wire 10 as like in the above-described embodiment. In addition, since almost the entire surface of the guide wire 10, with which the body tissue is brought into contact, is **covered with the electrically insulated coating** 25, the

> medical wire may be inserted into the patient's body without using any catheter. Ogawa (col. 9, lines 44-52) (emphasis added).

As explained above, parts 12 and 13 are portions of the guide wire 10, and the insulated coating 25 is applied to the peripheral surfaces of part of the guide wire 10.

Accordingly, the joint member 15 is located distally relative to the portions 12 and 13 that are coated with the coating 25, which is on or around portions of the guide wire 10. Ogawa (Fig. 6). Therefore, the insulated coating 25 (the alleged "insulative member") is not positioned between the joint member 15 (the alleged "temporary connection") and the implanted device 16 (the alleged "coil"), and the insulated coating 25 does not connect the joint member 15 (the alleged "temporary connection") and the implanted device 16 (the alleged "coil").

Further, a peripheral insulated "coating" as described by Ogawa, and as its name implies, is not suitable for being positioned between and connecting the joint member 15 and implanted device 16, particularly considering that Ogawa specifically explains that the insulted "coating" 25 is used for a specific, different purpose that is not related to the structural configuration recited in claim 29. Specifically, Ogawa explains that the purpose of the insulated coating 25 is to be able to insert the medical wire into a patient's body without the need for a catheter. Ogawa (col. 6, lines 50-52). Fig. 2 of Ogawa illustrates that the distal end of the joint member 15 is fixedly connected to a proximal portion 16A of the implanted device 16. Therefore, the insulated coating 25 is not related to, not suitable for, and not required for, connecting the joint member 15 (the alleged "temporary connection") and the implanted device 16 (the alleged "implant"), particularly considering that Ogawa explains that the joint member 15 is fixedly connected to the guide wire 10 by an adhesive and also fixedly connected to a coil portion of the implanted device 16 by an adhesive.

Therefore, as conceded in the Office Action, Ogawa fails to disclose, teach or suggest the "temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant" as recited in claim 29.

Given these very different structural configurations and functions, Applicants respectfully submit that the general, unsupported Office Action allegation that it would be obvious to have an insulative member positioned between and connecting a temporary connection and an implant in view of the unrelated disclosure of Ogawa is misplaced and fails to consider the particular configuration actually described by Ogawa, the very different and specific

purpose of the insulated "coating" (to eliminate a catheter) described by Ogawa, and the fact that such an "insulated coating" is not configured for and not necessary for connecting the joint member 15 and implanted device 16. Further, Ogawa specifically describes using an adhesive to connect the joint member 15 to the distal portion 14 of a guide wire 10 and proximal coil portion 16A of the implanted device 16.

Moreover, given the particular structural configuration of the insulated "coating" 25 and function thereof as described above, Ogawa teaches away from the "temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant" as recited in claim 29 since a "coating," as is well understood in the art, is not intended to be positioned between and connect a temporary connection and an implant.

Further, not only are the Office Action allegations inconsistent with what is described by Ogawa, but since Ogawa actually explains that the purpose of the coating 25 allows elimination of the catheter 20, Ogawa is not applicable to claim 29, which positively recites *inter alia* "a catheter having a proximal end and a distal end…" Ogawa describes a configuration that is the opposite of the configuration recited in claim 29and teaches away from claim 29 since the insulation coating 25 described by Ogawa is used for the purpose of eliminating a positively recited element in claim 29.

It is further alleged in the Office Action that the counter electrode 23 for body earth is an "electrical measurement device" as recited in claim 29 and a "current measurement device" as recited in claim 67. Claim 29 recites that the electrical measurement device is configured to monitor an electrical condition related to a position of the temporary connection while the temporary connection is joined to the delivery member and joined to the implant through the insulative member and to generate an output signal while the temporary connection is joined to the implant and in response to the changed electrical condition.

However, Ogawa does not actually explain, and the Office Action has not established, that the "counter electrode 23 for body earth" actually performs, or is configured to perform, the functions recited in claim 29. Rather, as shown in Fig. 5 of Ogawa, the electrode 23 appears to be a conventional ground or "body earth" electrode attached to a patient's body.

With regard to the "electrical measurement device" and other elements of claims that are not expressly disclosed by Ogawa, Applicants note the following sections or rules. 35 U.S.C. §132 ("Whenever on examination, any claim of a patent is rejected, . . . the Director shall notify

the application thereof, stating the reasons for such rejection, . . . together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application . . ."); 37 C.F.R. § 1.194(c)(2) ("In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. . . The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified."); MPEP §2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); MPEP §2163.07 (emphasis added) (To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP §2112, citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). *See also, Akami Tech., Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1188 (Fed. Cir. 2003) (A claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present).

In view of these substantial deficiencies and differences, Applicants respectfully submit that independent claim 29 is patentable over Ogawa. Dependent claims 30, 31, 37, 38, 43-45, 47-52, 54, 59-61, 64, 65 and 72 incorporate the elements of claim 29 and, therefore, are also believed patentable over Ogawa. MPEP §2143.03 (If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious). Ogawa is also deficient relative to various dependent claims.

For example, Ogawa fails to disclose, teach or suggest "the temporary connection comprising a temporary mechanical connection" as recited in claim 37. The subject application provides examples of mechanical connections including a spring loaded mechanical clasp, a non-resilient mechanical ball and clasp capturing mechanism, and a screw/fastener device. Ogawa, on the other hand, explains that proximal part 11 of the guide wire 10 is structured such that a

wire is exposed to form a terminal part 18 through which a high-frequency current can be applied. In this manner, the joint member 15 is melted and severed by heating with a high-frequency current, thereby detaching the implanted device 16 from the guide wire 10. Ogawa (col. 6, lines 34-37). Applicants note that claim 32 recites *inter alia* "an electrolytic connection" and claim 38 recites *inter alia* "the temporary connection comprising a temporary connection that is breakable by application of heat" as recited in claim 38.

With regard to claims 48-50, it is conceded in the Office Action that Ogawa fails to disclose a coil having a bio-reactive material coating. Instead, Ogawa explains that the implanted device 16 may include a coil piece that is formed of a platinum alloy and that may carry or hold suitable substances. Office Action (p. 4); Ogawa (col. 6, lines 50-61). 35 U.S.C. §132; 37 C.F.R. §1.194(c)(2); MPEP §2112.

With regard to claims 51 and 52, it is also conceded that Ogawa fails to disclose a "stent" or a "filter" as recited in these claims. 35 U.S.C. §132; 37 C.F.R. §1.194(c)(2); MPEP §2112.

The Office Action also fails to identify a section of Ogawa that discloses the elements of claim 54 (visual indicator). 35 U.S.C. §132; 37 C.F.R. §1.194(c)(2); MPEP §2112.

Moreover, the Office Action is understandably silent with respect to claim 64, which recites *inter alia*, "a conductive wire connected between the electrical measurement device and the distal end of the catheter, the electrical measurement device being configured to detect an electrical condition related to a position of the temporary connection, while joined to the implant, in the catheter through the conductive wire" and claim 65, which recites inter alia "the conductive wire being positioned through the catheter." 35 U.S.C. §132; 37 C.F.R. §1.194(c)(2); MPEP §2112. It is alleged that the grounding or counter electrode 23 to body earth is an "electrical measurement device." However, as shown in Fig. 5 of Ogawa, there is no wire connected between the grounding electrode 23 and a distal end of a catheter. If the rejection stands, Applicants request the Examiner to identify, by column and line number, the sections of Ogawa that allegedly disclose the components recited in claims 64 and 65 and the manner in which such components are structured.

Ogawa also fails to disclose, teach or suggest, and the Office Action has not identified any section of Ogawa that describes, "wherein the output signal is provided to a user, while the temporary connection is joined to the implant, to allow the user to manually initiate breaking of the temporary connection and to release the implant" as recited in claim 72. Rather, Ogawa

explains that current for detaching the implanted device is applied. Ogawa (col. 7, line 62 – col. 8, line 6). 35 U.S.C. §132; 37 C.F.R. § 1.194(c)(2); MPEP §2112.

In view of the above remarks, Applicants respectfully submit that the rejection of claims 29-31, 37, 38, 43-45, 47-52, 54, 59-61, 64, 65 and 72 under 35 U.S.C. §103 be withdrawn.

IV. Claims 32-36, 41, 42, 46, 55, 57 and 66 Are Patentable Over Ogawa and Scheldrup

Dependent claims 32-36, 41, 42, 46, 55, 57 and 66 (which depend from independent claim 29), independent claim 67, and dependent claims 68-71 and 73 (which depend from independent claim 29, stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ogawa in view of Scheldrup. Scheldrup is cited for limited purposes, but does not cure the substantial deficiencies of Ogawa with respect to independent claim 29 as discussed above. Consequently, even if the alleged combination were somehow made, the combination would nevertheless fail to disclose each and every limitation of independent claim 29 and the rejected dependent claims.

Accordingly, Applicants respectfully submit that the rejection of claims 32-36, 41, 42, 46, 55, 57 and 66 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

V. Claims 67-71 and 73 Are Patentable Over Ogawa and Scheldrup

Independent claim 67 and dependent claims 68-71 and 73, which depend from independent claim 67 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ogawa in view of Scheldrup.

Claim 67 includes elements that are the same or similar to elements of claim 29 discussed above in Section III. Applicants respectfully submit that the rejection of claims 67-71 and 73 is moot in view of the above remarks.

Further, it is apparently alleged that a current measurement device" as recited in claim 67 is the counter or ground electrode 23. However, Ogawa does not explain that the electrode 23 is configured to, or even capable of, monitoring electrical current as the delivery member is pushed through the catheter and generating an output signal in response to detecting the second current level. Rather, as discussed above, the electrode 23 is conventional ground or "body earth" electrode attached to a patient's body. Ogawa (col. 7, lines 56-57). 35 U.S.C. §132; 37 C.F.R. § 1.194(c)(2); MPEP §2112.

Accordingly, Applicants respectfully submit that the rejection of claims 67-71 and 73 under 35 U.S.C. §103(a) be withdrawn.

VI. Claim 39 Is Patentable Over Ogawa and Guglielmi

Dependent claim 39 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ogawa in view of Guglielmi. Guglielmi is cited for the limited purpose of allegedly disclosing temporary connections broken by heat and RF radiation. Guglielmi, however, does not cure the deficiencies of Ogawa with respect to independent claim 29. Accordingly, even if the alleged combination were made, the combination would fail to disclose each and every limitation of claims 29 and 39. Accordingly, Applicants respectfully submit that the rejection of claim 39 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

VII. Claim 40 Is Patentable Over Ogawa and Sepetka

Dependent claim 40 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ogawa in view of U.S. Patent No. 5,814,062 to Sepetka *et al.* ("Sepetka"). Sepetka is cited for the limited purpose of allegedly disclosing a connection that is hydraulically broken. Sepetka, however, does not cure the deficiencies of Ogawa with respect to independent claim 29. Accordingly, even if the alleged combination were made, the combination would fail to disclose each and every limitation of claims 29 and 40. Accordingly, Applicants respectfully submit that the rejection of claim 40 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

VIII. Claims 62 and 63 Are Patentable Over Ogawa and Cheng

Dependent claims 62 and 63 (which depend from claim 29) stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ogawa in view of U.S. Patent No. 6,296,636 to Cheng *et al.* ("Cheng"). Cheng is cited for the limited purpose of allegedly disclosing a comparison circuit that compares a threshold current to a current measured by an electrical measurement device. Cheng, however, does not cure the deficiencies of Scheldrup and Alt with respect to independent claim 29. Therefore, dependent claims 62 and 63 are believed patentable. Accordingly, Applicants respectfully submit that the rejection of claims 62 and 63 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

CONCLUSION

Applicants respectfully submit that the application is in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicants invite the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,

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